REMARKS

Please amend claim 37 and add new claims 38-42 as follows:

By the foregoing amendment, applicant has amended claim 37 to more particularly point out and distinctly claim the subject matter that applicant regards as the invention and has added new claims 38-42. New claims 38-42 find support in the original specification, for example in the percentages as found in Table 1A and in paragraphs [0019] – [0024].

After entry of the foregoing amendment, claims 1-4, 6-8, 31 and 33-42 remain pending in the application.

Applicants appreciate the withdrawal of the previous rejection of the claims on the combination of Blume et al (U.S. Patent 6,372,252) in view of Dansereau et al (U.S. Patent 5,032,406). This withdrawal of the rejection is a tacit admission that the previous claims were not obvious over the combination of Blume and Dansereau.

The foregoing deficiencies of Blume et al and Dansereau et al in failing to establish a *prima facie* case of obviousness of the claims under 35 U.S.C. 103 (a) are not corrected by the addition of Troy et al (U.S. Patent 3,627,583) and Ansel et al (pharmaceutical dosage forms) as set forth in paragraph 2 of the previous Office Action.

Reconsideration of this rejection is respectfully requested in view of the following comments.

Although the Examiner states (page 3, lines 3-6 of the previous Office Action that "the resulting material of Blume reads on the agglomerated mixture, because the processing of the material describes the same steps as described in instant application)" is erroneous. If the resulting material of Blume et al read on the claimed agglomerated mixture, there would have been no reason to cite Dansereau in the preceding Office Action nor the combination of Dansereau, Troy and Ansel, as in the present rejection.

In fact, Blume fails to teach any agglomerated mixture of guaifenesin which would comprise 85% by weight to about 97.5% by weight guaifenesin as set forth in the independent claims 1, 31, 37, and 38 of the instant application.

In addition, the Examiner has conceded (page 3, line 6 of the current Office Action) that "Blume fails to teach granulation of guaifenesin with polyvinyl pyrrolidone. Although Danserereau is cited to show that polyvinyl pyrrolidone can be added to a guaifenesin composition, it still fails to show the composition comprising between 85-95.5% by weight guaifenesin as instantly claimed. Thus the proposed combination of Blume with Dansereau still does not establish a *prima facie* case of obviousness for the claimed invention.

Neither of the newly cited Troy or Ansel references correct this deficiency.

Troy is not at all directed to compositions comprising guaifenesin. In fact, Troy is solely directed to compressing sugar agglomerates for production of tablets (see column 1, lines 53-55) and would not at all teach those skilled in the art how to form a high content particulate guaifenesin composition comprising between 85-97.5% by weight guaifenesin as instantly claimed in each of the independent claims. The Ansel et al reference is even further removed from the claimed invention and

clearly removed from the environment of the claimed invention in which a high dosage form guaifenesin composition is prepared because Ansel et al does not even disclose any medicaments whatsoever. Thus the proposed combination of these four references clearly fails to establish a *prima facie* case of obviousness of the claimed invention and the Examiner does not even suggest how one having an ordinary skill in the art would be able to obtain such high dosage forms of guaifenesin compositions from the combined teachings of the cited references.

All that the Examiner has attempted to do is find isolated bits and pieces of the invention from among the collection of art that the Examiner has searched, but even when that collection is combined, it still does not establish the limitations of the claimed invention. For example, the Examiner attempts to cite Troy and Ansel as showing agglomerates ranging in particle size from "about 325 to about 12 mesh" [about 1.68mm to about 44 microns-source Perry's Chemical Engineers Handbook, sixth edition, cited in applicant's last response] and column 1, lines 59-61 of Troy. However, such teachings do not correct the deficiencies of Blume and Dansereau. Applicant's claims and particularly the particle size distribution as recited in claims 37, 38, and 42 clearly distinguish the particle size distribution as limitations of the claims. More importantly, Troy et al is directed to tableting sugar, not guaifenesin and thus his teachings of agglomerate size for sugar has no relation to the instantly claimed invention. Ansel is even further removed as Ansel teaches, page 221 right hand column of "Sizing the Granulation by Dry Screening" that screens from 12 -20 mesh size are generally used for this purpose" [1.68 mm – 841 microns-source Perry's Handbook previously cited] which are clearly excluded by all of the instant claims. In fact, as the Examiner cites, at the foot of page 4 of the Office Action, Ansel states "that one reason for capping of tablets is a granulation which has too great a proportion of fines or fine powder" whereas in the claimed invention, almost all of the particle size distribution is much smaller than the smallest size permitted

by Ansel et al.

Accordingly there is nothing in the proposed combination of references that would even hint at producing a high weight guaifenesin tablet for agglomerates of guaifenesin and polyvinyl pyrrolidone from a composition as instantly claimed. Thus, it can be seen that even though the Examiner has cobbled together 4 references, the totality of the teachings of these references still fail to show either: the percentage of guaifenesin or the particle size distribution of agglomerates of guaifenesin and polyvinylpyrrolidone binder. Thus, there can clearly be no *prima facie* case of obviousness established for the claimed invention.

In response to the Examiner's arguments, it is apparent the Examiner has conceded the "instant claims are not rejected over Blume and Dansereau" (see the last sentence at the foot of page 8) instead, they are rejected in view of the new combination of references, particularly Troy and Ansel.

However, as noted above, Troy is directed with compressing, not a drug, but sugar, and Ansel et al teach away from the claimed invention by showing a lower limit of 20 mesh and the abborance of particles smaller than 20 mesh which is completely contrary to the claimed invention. Thus, the citation of the Troy and Ansel references clearly does not correct the Examiner's admitted deficiency in the combination of Blume and Dansereau. Accordingly, the application is now in condition for immediate allowance which action is earnestly solicited.